



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Murphy, et al.

Serial No. : 09/886,400

Filed : June 20, 2001

Title : ALPHA GALACTOSIDASES AND METHODS FOR MAKING AND USING THEM (Amended)

Art Unit : 1633 1652 *WHL*

Examiner : Delia M. Ramirez, Ph.D.

Commissioner for Patents
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. §1.132

1. I, Walter Callen, having an address at 3469 Stetson Ave., San Diego, CA 92122, am a Staff Scientist II, at Diversa Corporation since June 20, 1994. As a staff scientist, my responsibilities at Diversa include overseeing research projects and ensuring that the laboratory runs efficiently and effectively.

2. During the week of September 2, 2002, I prepared the plasmid 18GC in *E. coli* M15 pREP4 for deposit with the ATCC, located at 10801 University Blvd., Manassas, VA 20110-2209. The Patent Deposit Designation is PTA-4654. A copy of the notification from a representative of the ATCC acknowledging acceptance of the deposit is attached.

3. The deposited material is the same as that described in the specification of the instant application at page 5, lines 2-5, as well as the applications to which this application claims priority, *i.e.*, U.S. Patent Application Serial No. 09/619,032, filed July 19, 2000, which is a divisional of U.S. Patent Application Serial No. 09/407,806, filed September 28, 1999, which is a divisional of U.S. Patent Application Serial No. 08/613,220, filed March 8, 1996, issued as Patent No. 5,958,751.

4. I believe this to be true because, as is our standard practice, on February 24, 1995, the original library containing the 18GC clone was prepared. In approximately June, 1995, the library was screened for alpha-galactosidase activity, yielding 18GC as one of the clones with alpha-galactosidase activity. The clone was then isolated, labeled as "18GC1", and

one portion was stored in a glycerol stock at -80°C and another portion was sent for sequencing. The clone was disclosed in U.S. Patent Application Serial No. 08/613,220, filed March 8, 1996.

From the frozen glycerol stock, a portion was recultured and the DNA isolated. This DNA was used for construction of an over-expression clone, also called a subclone. In this over-expression construct, the ORF (Open Reading Frame) was put under the control of an inducible promoter, the start codon was changed to 'ATG' and a C-terminal tag of six Histidine residues were added. The 18GC subclone was assigned a new name, 18GC1.11.1QET1. This subclone was prepared in a 15% glycerol stock, divided into 3 aliquots (1 ml aliquots in 1.5 ml vials), labeled as "GLY001-10, 18GC1.11.1QET1, 6/17/97" and stored at -80°C . Two of the vials were sent off-site for storage and 1 vial remained at Diversa.

When it was time to prepare the 18GC subclone for ATCC deposit, I went to the person in charge of maintaining all of the frozen clones and subclones, requested vial containing the 18GC subclone. I thawed the 18GC sample and took a loop of it to start a culture. Once the 18GC subclone culture attained sufficient growth, I prepared 30 glycerol stocks of the culture and froze them for shipment to the ATCC for deposit. On September 9, 2002, Lynn Linkowski, of Diversa Corporation, coordinated and executed the deposit of the glycerol stocks of 18GC with the ATCC. The samples were received by ATCC on September 10, 2002, and assigned Patent Deposit Designation PTA-4654.

5. Accordingly, I submit that the deposited material, PTA-4654, was in our possession at the time of filing of the instant application, as well as the filing of the earliest priority application, and that the deposited material is the same material as that described in the specification as 18GC.


6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

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Attorney's Docket No.: 09010-004005

Respectfully Submitted

Date: 12/17/02

A handwritten signature in dark ink, appearing to read 'Walter Callen', written over a horizontal line.

Walter Callen
Staff Scientist II



ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

**BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE**

INTERNATIONAL FORM

**RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2**

To: (Name and Address of Depositor or Attorney)

DIVERSA Corporation
Attn: Lynn Linkowski
4955 Directors Place
San Diego, CA 92121

Deposited on Behalf of: DIVERSA Corporation

Identification Reference by Depositor:

Patent Deposit Designation

Plasmid: 18GC in E.coli M15 pREP4

PTA-4654

The deposit was accompanied by: ☐ a scientific description ☐ a proposed taxonomic description indicated above.

The deposit was received September 10, 2002 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: ☒ We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested September 18, 2002. On that date, the culture was viable.

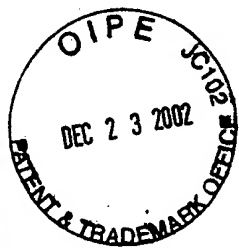
International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Marie Harris
Marie Harris, Patent Specialist, ATCC Patent Depository

Date: October 10, 2002

cc: Gregory Einhorn
(Ref: Docket or Case No.: 09010-004004)



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DECLARATION FOR A DEPOSIT MADE UNDER THE BUDAPEST TREATY

1. I, Mi Kim, having an address at 4350 La Jolla Village Drive, Suite 500, San Diego, CA 92122, am the attorney of record of the above-referenced United States patent application serial no.09/886,400. I declare that:

2. A deposit of plasmid 18GC in E. coli M15 pREP4 has been made on September 10, 2002, with the ATCC, located at 10801 University Blvd., Manassas, VA 20110-2209. The Patent Deposit Designation is PTA-4654.

3. The deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, as indicated in the attached notification.

4. All restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application.

5. The deposit will be replaced if viable samples cannot be dispensed by the depository as required.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

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United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully Submitted

Date: 12/18/2002

Mi Kim
Mi Kim
Reg. No. 44,830